

blocker in combination with a selective serotonin uptake inhibitor and the use of the composition for the treatment of inflammation or intracranial edema.

Group IV: Claims 1-8 (in parts), 10-15 (in parts), 17 (in parts) and 18-23 (in parts), directed to a pharmaceutical composition which comprises a sodium channel blocker in combination with a selective serotonin uptake inhibitor and the use of the composition for the treatment of itching.

Group V: Claims 1-8 (in parts), 10-15 (in parts), 17 (in parts) and 18-23 (in parts), directed to a pharmaceutical composition which comprises a sodium channel blocker in combination with a selective serotonin uptake inhibitor and the use of the composition for the treatment of ischemia and/or subsequent damage caused by reperfusion or retinopathy as a complication of glaucoma.

Group VI: Claims 1-7 and 9 (in parts), 10-15 (in parts), 16 (in parts) and 18-23 (in parts), directed to a pharmaceutical composition which comprises a sodium channel blocker in combination with a selective serotonin uptake inhibitor and the use of the composition for the treatment of chronic pain.

Group VII: Claims 1-7 and 9 (in parts), 10-15 (in parts), 16 (in parts) and 18-23 (in parts), directed to a pharmaceutical composition which comprises a sodium channel blocker in combination with a selective serotonin uptake inhibitor and the use of the composition for the treatment of epilepsy.

Group VIII: Claims 1-7 and 9 (in parts), 10-15 (in parts), 16 (in parts) and 18-23 (in parts), directed to a pharmaceutical composition which comprises a sodium channel blocker in combination with a selective serotonin uptake inhibitor and the use of the composition for the treatment of symptoms or diseases deriving from disorders and/or injuries of the motor system.

The applicants hereby elect, *with traverse*, the invention of Group VI, claims 1-7 and 9 (in parts), 10-15 (in parts), 16 (in parts) and 18-23 (in parts), directed to a pharmaceutical composition which comprises a sodium channel blocker in combination with a selective serotonin uptake inhibitor and the use of the composition for the treatment of chronic pain.

The Examiner has correctly noted that the present application is a national stage application of a PCT application, and thus unity of invention practice (not restriction) is

applicable. However, the Examiner has improperly applied the unity of invention standard. Contrary to the Examiner's position, the claimed invention is drawn to a single general inventive concept: the parallel administration of sodium channel blockers and selective serotonin uptake inhibitors. The applicants unexpectedly found that a marked increase in the sodium channel blocking activity was obtained when a serotonin uptake inhibitor is administered simultaneously. As noted in the specification (see page 4, third full paragraph), these new compositions are effective in the therapy of diseases which are therapeutic targets for sodium channel blockers – thus the common link between the diseases being treated by the invention is that they are treatable by sodium channel blockers. It is proven by the experimental section, and it is clear from the description, that the presence of the small amount of selective serotonin uptake inhibitor does not change the target or the separate inventions based on the different treatments.

Thus, the single general inventive concept that ties all of the claims together is the co-administration of sodium channel blockers and selective serotonin uptake inhibitors – not the various conditions being treated, as the Examiner appears to assert. As noted in Sec. 1893.03(d) of the MPEP:

A group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. The expression special technical features is defined as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art.

Here, the “special technical feature” is the finding that by co-administering the sodium channel blocker with a selective serotonin uptake inhibitor, a marked increase in the sodium channel blocking activity is obtained. This single feature is what distinguishes each of the inventions over the prior art, and thus is a single general

inventive concept. Thus, a Restriction Requirement in this case is improper, under 37 C.F.R. § 1.499, and should be withdrawn.

Election of Species

The Examiner has also required that an election of species be made from the following:

A) various sodium channel blockers (e.g. lamotrigine, crobenetine, oxcarbamazepine and fosphenytoin); and

B) various selective serotonin uptake inhibitors (e.g. fluoxetine, sertraline, escitalopram, etc.).

Applicants hereby elect for examination the sodium channel blocker lamotrigine and the selective serotonin uptake inhibitor sertraline. Claims readable on the use of lamotrigine include claims 1-4, 6, 8-12, 14, 16-20 and 22. Claims readable on the use of sertraline include claims 1-3, 6-11, 14-19 and 22-23. This election is made *with* traverse. This requirement is traversed to the extent that examination may not be conducted pursuant to the guidelines set forth at MPEP Sec. 803.02. Applicants reserve their right to traverse if the procedure outlined in this section of the MPEP is disregarded.

Conclusion


Examination and further and favorable consideration of this Application is respectfully requested.

Applicants respectfully request that the Examiner reconsider the restriction requirement and that it be withdrawn.

Applicants believe that the present Application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

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Date: May 21, 2009

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